



ASX Announcement

January 13, 2020

Completion of Exenatide Phase II Clinical Trial

Invex Therapeutics Ltd (Invex, ASX: IXC, or the Company) is pleased to announce the last patient has completed the 12 week dosing regimen under the Company's randomised Phase II, double-blind, placebo-controlled clinical trial examining the treatment of Idiopathic Intracranial Hypertension (IIH) with Exenatide.

The Phase II clinical trial has been designed to demonstrate that Exenatide can significantly reduce intracranial pressure in IIH patients, and to gather data which will be necessary to design a subsequent registration-directed, single pivotal trial to gain regulatory clearance for the Company's reformulated Exenatide in IIH in the United States (US) and Europe. Exenatide has orphan drug designation in the US (FDA) and Europe (EMA).

Having completed patient dosing ahead of schedule, the Company is pleased to confirm that it now expects top-line results for the Phase II trial in late Q1 2020 to early Q2 2020.

Chairman Dr Jason Loveridge commented: "The completion of the Phase II clinical trial for Exenatide represents an important milestone for Invex, its shareholders and patients living with the burden of IIH. We eagerly await the independent analysis of our study findings and the reporting of our clinical results to the market."

This release dated 13 January has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics and lodged by Narelle Warren, Company Secretary.

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About Invex Therapeutics Ltd

Invex is a biopharmaceutical company focused on the repurposing of an already approved drug, Exenatide, for efficacious treatment of neurological conditions derived from or involving raised intracranial pressure, such as Idiopathic Intracranial Hypertension (IIH), acute stroke and traumatic brain injury. www.invextherapeutics.com.

About Idiopathic Intracranial Hypertension

IIH features severely raised intracranial pressure which causes disabling daily headaches and can compress the optic nerve, causing permanent vision loss in 25% of those affected. The usual age of onset is 20-30 years, and it is most common in women who are obese. IIH is a rapidly growing orphan indication: its incidence has increased by more than 350% in the last 10 years.

About Exenatide

Exenatide is a small peptide and a synthetic version of the GLP-1 agonist exendin-4, which received approval in the US and Europe for the treatment of type 2 diabetes in 2005 and 2006 respectively. Professor Alexandra Sinclair's research showed that GLP-1 receptors are expressed in the choroid plexus in the brain and that Exenatide can bind to these receptors and reduce secretion of cerebrospinal fluid. Current Exenatide dosage forms are not optimised for IIH.

About Exenatide Phase II Clinical Trial

The Exenatide clinical trial in IIH is a single centre, randomised Phase II, double-blind, placebo-controlled clinical trial in 16 patients with active IIH comparing sub cutaneous (s.c.) 10 mg Exenatide twice daily with placebo. The primary endpoint of the study is the change in intracranial pressure over 12 weeks of dosing as measured by real-time patient monitoring devices.